PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

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PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/IT2004/000217	15.04.2004	22.04.2003

International Patent Classification (IPC) or both national classification and IPC
G06T5/00

Applicant
PROVINCIA ITALIANA DELLA CONGREGAZIONE DEI...

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:

European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4465

Authorized Officer

Martelli, Luca

Telephone No. +49 89 2399-7416

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/IT2004/000217

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was field, unless otherwise indicated under this item.

   ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

   ☐ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material:

   ☐ in written format

   ☐ in computer readable form

   c. time of filing/furnishing:

   ☐ contained in the international application as filed.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

Box No. II Priority

1. ☒ The following document has not been furnished:

   ☒ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).

   ☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).

   Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 1-6,9-18

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination *(specify)*:

☒ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. 1-6,9-18 are so unclear that no meaningful opinion could be formed *(specify)*:

see separate sheet

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the whole application or for said claims Nos.

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form ☐ has not been furnished

☐ does not comply with the standard

the computer readable form ☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	7,8
	No:	Claims	
Inventive step (IS)	Yes:	Claims	7,8
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	7,8
	No:	Claims	

2. Citations and explanations

see separate sheet

CITED DOCUMENTS

The following documents are referred to in this communication:

D1: WO 02/33649 A	(Souluer Farid)	25 April 2002	(2002-04-25)
D2 : US 5 836 872 A	(Tearney GJ et al)	17 November 1998	(1998-11-17)

Re Item III

III.1 Independent claim 1

It is clear from the description (see page 13, lines 1-29) that the features mentioned in the **claims 5-7** are necessary to the definition of the invention. Since it does not include these features, **the independent claim 1 does not meet the requirements following from Article 6 PCT** taken in combination with Rule 6.3(b) PCT that any independent claim must contain all the technical features which are essential to the definition of the invention.

III.2 Dependent claims 2-6 and 9-11

These claims depend on claim 1 and as such do not fulfil the requirements of Article 6 PCT for the reasons explained on point III.1 above.

III.3 Independent claim 12

It is clear from the description (see page 13, lines 1-29 and page 16, lines 7-10) that **means for carrying out the method steps of claims 5 and 7** (the method claim 6 does not require special apparatus features) are necessary to the definition of the invention. Since it does not include these features, **the independent claim 12 does not meet the requirements following from Article 6 PCT** taken in combination with Rule 6.3(b) PCT that any independent claim must contain all the technical features which are essential to the definition of the invention.

III.4 Dependent claims 13-18

These claims depend on claim 12 and as such do not fulfil the requirements of Article 6 PCT for the reasons explained on point III.3 above.

Moreover, the claims 14 and 16-18 do not fulfil the requirements of Article 6 PCT because, in addition to the above reason, they relate to a method of using the apparatus ("it is controlled and managed in a completely automatic way"; "the position and the orientation ... are stored"; "the positions ... are calculated so that ...") rather than clearly defining the apparatus in terms of its technical features, thus making the intended limitations not clear from these claims.

Re Item V

V.1 Dependent claim 7

D1 discloses a method of detecting and showing variations in the number and morphology of skin lesions (see page 1, lines 18-19 and page 25, line 30 to page 26, line 1), wherein, in order to automate the detection and the transmission of said variations,
- digital images of the body surface of the tested subject are collected (see page 10, line 67 and page 21, lines 15-16) after having divided the latter into one or more areas (see page 9, line 1 and page 21, lines 16-17) exactly located by means of spatial coordinates in a system of coordinated axes fixed with respect to predetermined unchanged reference point of the subject (i.e. body parts such as shoulders, arms and neck: see page 9, lines 11-22, as well as page 10, lines 1-8; page 21, lines 17-18; page 24, lines 15-16),
- the images being stored in a suitable data base (see page 24, lines 16-19)
- to be then compared with corresponding images collected at distance of time (see page 10, lines 7-8 and page 24, line 19),
- thus producing a signal of any variation in the number, morphology and colour of the lesions (see page 24, line 28 to page 25, line 3) and wherein, in order for any variation of the collected images not relating the state of the skin lesions to suppressed or minimised,
- the spatial positions of the detection apparatus and the tested subject are constant in order for any variation of the collected images not relating the state of the skin lesions to be suppressed or minimised (see page 9, line 20).

The subject-matter of claim 7 is characterised over D1 in that the segmentation of the body into images is performed so that the edges of the images are partially overlapped so as to allow a comparison even when modifications of the body of the tested subject take place between subsequent tests.

Since the expression "segmentation of the body" is not defined, **this claim is not clear within the meaning of Article 6 PCT**; the present remarks are based on what can be understood from the description, see page 11, line 28 to page 12, line 8.

The problem to be solved may be considered as to ensure that images are taken of the selected body parts even if the dimensions of the patient vary during different tests (see the description, page 13, lines 21-25).
This problem and the corresponding solution are not addressed in the available prior art documents. Hence, if claim 7 were clarified in the sense indicated above, it would fulfil the requirements of Article 33(2) and (3) PCT.

Claim 8 depends on claim 7 and as such would also meet the requirements of PCT with respect to novelty and inventive step if the unclear passages were amended as mentioned above.

V.2 Independent claim 12

Although the independent claim 12 is not examined owing to the lack of clarity explained on point III.3 above, it is pointed out that D1 describes an apparatus for detecting images of skin lesions (10, see page 1, lines 23-24), the apparatus comprising:

- an application software for processing fine graphic data provided with algorithms able to provide a discrete set of the detected images (see page 20, lines 27-29);
- a data base for the statistic analysis of data of interest (see page 24, lines 16-17);
- a data processing portion for clinic, personal data of the subjects for storing and listing the images of each patient upon his/her visiting (see page 24, lines 16-17);
- a reference surface (66, 71) provided with anthropometrical references with respect to which the tested subject is positioned (see page 9, lines 4-6);
- means for lighting uniformly (136) without shadows the zones of the subject body

surface to be detected (see page 10, lines 9-14);
- image collection means (134, see page 10, line 6);
- means for supporting the image collection means with respect to the patient (see figure 5; means for driving under control: see D2, column 11, lines 36-46);
- interface means for controlling the data collection and transmission to suitable storing and processing means (see page 7, lines 6-7);
- a computer connected to such interface means (see page 10, line 7);
- a high definition monitor (see page 7, lines 7-9);
- means for controlling the correct repositioning of the subject (see page 9, line 29 to page 10, line 5).

Hence D1 describes all the features of claim 12.